

SEP - 6 2001

K003988

510(k) Summary (21CFR807.93) Application: UroScope (Endoscope/Cystoscope)

Date of Application: December 22, 2000

Company Name Artes Medical USA, Incorporated
and Address: 4660 La Jolla Village Drive
 Center 1, Suite 825
 San Diego, CA 92122

Contact Person: William Kirkpatrick, Ph.D.
 Director of Regulatory and Quality
Telephone: (858) 550-9999
Fax: (858) 550-9997
E-mail: billkirk@artemedical.com

A. Indication for Use

The UroScope is used to examine the lower urinary tract of the adult female and, using additional devices, to perform various diagnostic and therapeutic procedures

B. Summary of Safety and Effectiveness

The UroScope was compared with other brands of cystoscopes and found to be equivalent. Patient contact surfaces are composed of a material which has been qualified by biocompatibility testing.

C. Parts of Finding Substantial Equivalence

Principles of operation, design and clinical use are equivalent to the standard cystoscope. For example, the UroScope employs a cylinder to expand the urethra in a manner similar to the cystoscope and provides an optical magnification and fiber optic light transmission pathway for visualization of the urinary tract like the cystoscope.

D. Descriptive Information

The UroScope is a specialized type of cystoscope designed to facilitate examination, diagnosis and therapy of the lower urinary tract in the adult female. The UroScope consists of two components; a multiple use handle and a single use, disposable magnifying lens/insertion cone.

E. Adverse Health Effects

The sponsor is not aware of any actual or potential adverse health effects associated with use of the UroScope.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP - 6 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

William Kirkpatrick, Ph.D.
Director of Regulatory and Quality
Artes Medical, Inc.
4660 La Jolla Village Drive, Suite 825
SAN DIEGO CA 92122

Re: K003988
UroScope, Artes Medical, USA
Dated: August 20, 2001
Received: August 24, 2001
Regulatory Class: II
21 CFR 878.1500/Procode: 78 FAJ

Dear Dr. Kirkpatrick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K003988

Device Name: UroScope, Arties Medical, USA

Indications For Use: Arties Medical, USA UroScope, is intended to provide visualization of the Lower urinary track of the adult female and, using additional accessories, to perform various Diagnostic and therapeutic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K003988

(Optional Format 3-10-98)

Prescription Use ✓